## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jillian Jacobson-Altit

Serial No.: 10/718,213 Group Art Unit: 1615

Filed: November 20, 2003 Examiner: M. S. Mercier

For: MULTI-SENSORY PLEASANT LIP GLOSS

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## DECLARATION UNDER 37 CFR 1.132

My name is Ira S. Jacobson.

- 1. I am a medical doctor having received the degree of Doctor of Medicine from the University of Oregon Medical School in 1969. I have experience working in a bacteriology laboratory and I am also familiar with the disclosure of patent Application 10/718,213, filed by Jillian Jacobson-Altit and with Shanni US Patent No. 5,631,012 that I am advised has been cited against of Ms. Jacobson-Altit's application.
- 2. After an interview at the Patent and Trademark Office that I am advised Ms. Jacobson-Altit's attorney, Robert L. Stone, had with Examiners Mercier and Gollimudi on July 10, 2007, I was asked by Mr. Stone to prepare samples of Ms. Jacobson-Altit's lip gloss composition and compare them at ambient temperature and at elevated temperature with corresponding compositions containing vernix, a material described in the Shanni patent and proposed for inclusion in a lip gloss. Because of concern as to safety of vernix I only applied the formulations to my fingers and not to my lips.

3. Accordingly I evaluated the following compositions, each of which I placed in two separate glass containers and removed samples for timely evaluations with a lip gloss applicator:

#1. Jacobson-Altit Composition (parts by volume):

Petrolatum	55.0			
Polybutene	20.0			
Isopropyl palmitate	13.25			
Ozokerite	2.0			
Sorbitan sesquioleate	1.0			
Natural flavor	0.3			
Fragrance	0.5			
Methyl paraben	0.2			
Propyl paraben	0.1			
Butylated hydroxytoluene (BHT)	0.2			
Colorants and pigments				
CI 15850	0.55			
CI 19140	0.65			
Mica	3.0			
CI 77163	1.3			
Silica	1.0			
CI 75470	0.3			

- #2 Composition 1, above, with 10 parts by volume of vernix incorporated therein.
- #3 Composition 1, above, with 25 parts by volume of vernix incorporated therein.
- #4 Composition 1, above, with 50 parts by volume of vernix incorporated therein.
- 4. Vernix, used in compositions #2, #3 and #4 were obtained from a hospital delivery room as it was scraped from the skin of newborn infants by the delivery room nurses and stored in sterile containers, under refrigeration, until put to use as described herein. Samples of vernix were cultured by inoculation application to standard media for vaginal cultures. Included in the procedure were several types of blood agar plates and a liquid broth media. Prior to preparation of samples #2, #3 and #4, culture samples were incubated at 37°C for 2 weeks. No bacterial growth was observed during this period.
- 5. Each of Compositions #1, #2, #3 and #4 were divided into two parts, observed initially and then one part of each was aged under ambient conditions and the other part of each was aged at 37°C. Each was observed at intervals with observations set forth below.

## Ambient Temperature

No. of weeks Composition #1 #2 #3 Initial Pleasant Acceptable Same as #2 Same as #2 Fragrance and fragrance and good color good color Applied and Applied and adhered well adhered well Same as #2. Same as #2. Unchanged Unchanged Same as #3 Unchanged Fragrance less Pleasant frapleasant grance masked 3 Unchanged Pleasant fragrance Same as #2 Same as #2. masked Same as #2 4 Unchanged Pleasant fragrance Same as #2 masked 6 Unchanged Pleasant fragrance Same as #2 Same as #2 masked Unchanged Pleasant fragrance Same as #2 Same as #2 masked Same as #2 Same as #2 10 Unchanged Pleasant fragrance masked Same as #2 13 Unchanged Pleasant fragrance Same as #2.

masked

## 7. Temperature-37°C

No, of weeks		Composition		
	#1	#2	#3	#4
Initial	Pleasant Fragrance and good color Applied and adhered well	Acceptable fragrance and good color Applied and adhered well	Same as #2	Same as #2
1	Unchanged	Unchanged	Same as #2	Unpleasant odor Otherwise unchanged
2	Unchanged	Faint odor Otherwise unchanged	Unpleasant odor Otherwise unchange	Same as #3
3	Unchanged	Unpleasant odor Otherwise unchanged	Same as #2	Same as #2
4	Unchanged	Unpleasant slight odor Otherwise unchanged	Same as #2	Noxious odor
6	Unchanged	Unpleasant odor Otherwise unchanged	Slight odor Otherwise unchang	Same as #3 ed Sticky
8	Unchanged	Unpleasant slight odor Otherwise unchanged	Bad odor Stringy	Noxious odor Sticky
10	Unchanged	Unpleasant odor	Unpleasant odor Sticky	Noxious odor Sticky
13	Unchanged	Unpleasant odor Stringy and sticky	Noxious odor Stringy and sticky	Unpleasant odor Stringy and sticky

8. Based upon the observations set forth above it was seen that Composition #1 remained a cosmetically very satisfactory lip gloss under the aging conditions, while vernix compositions #2, #3 and #4 underwent various types of cosmetic deterioration at ambient temperature, particularly having the pleasant fragrance of composition #1 quickly masked at ambient temperature. At elevated temperature vernix compositions #2, #3 and #4 underwent severe esthetic deterioration including unpleasant and even noxious odors that masked the pleasant fragrance of composition #1, as well as becoming unduly stringy and sticky, making it unsuitable for applications to the lips. This is particularly the case when it is considered that elevated temperatures can generally duplicate what occurs for longer periods of time at ambient temperature and also since compositions such as lip glosses can routinely be kept under warm and hot conditions such as in automobile glove compartments.

- 9. Based further upon the observations set forth above I conclude that lip gloss compositions containing vernix, a material that forms to protect a late term fetus but is typically quickly washed away as part of neonatal care, following childbirth, do not provide the long term stability needed for cosmetic compositions that are frequently stored and used over long periods of time and are often kept under high temperature conditions, for instance, when stored in an automobile glove compartment.
- 10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further that willful false statements are punishable by fine or imprisonment or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

January 23, 2008

/Ira S. Jacobson/